

(PCT Article 36 and Rule 70)

Date of submission of the demand	Date of completion of this report
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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/018895

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-24 as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the claims:
- nos. 2-5, 7, 8, 10, 12, 14, 15, 17-26 as originally filed/furnished
- nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- nos.\* 1, 9, 11, 13, 16 received by this Authority on 17.10.2005
- nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the drawings:
- sheets Fig. 1-21 as originally filed/furnished
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☒ the claims, nos. 6
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-5, 7-26	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-5, 7-26	NO
Industrial applicability (IA)	Claims	1-5, 7-26	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
<p>Document 1: JP 3-259096 A (Torii Pharmaceutical Co., Ltd.), 19 November 1991 (Family: none)</p> <p>Document 2: JP 2003-502641 A (Acaris Healthcare Solutions PLC) &amp; EP 1190245 A1 &amp; WO 2000/077516 A1</p> <p>Claims 1, 2, 4 and 5</p> <p>Document 1 sets forth the a method of determining the amount of allergen in room dust containing mites by measuring the extinction coefficient using a luminescent substrate with protease activity of a phosphoric acid buffer solution extract sample of room dust as an indicator.</p> <p>In the inventions set forth in claims 1, 2, 4 and 5, the allergen in the sample to be measured is brought into contact with the protease substrate "without carrying out pre-treatment", while in document 1, the sample to be measured is brought into contact with the protease substrate after carrying out extraction in a phosphoric acid buffer solution, which constitutes a difference between the inventions.</p> <p>In analyzing samples, it is a commonly encountered problem to eliminate pretreatment steps such as separation and refining of samples in order to simplify</p>			

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

analysis, therefore it would be easy for a person skilled in the art to conceive of merely eliminating pretreatment steps without making any other particular modifications, and even if doing so revealed that the pretreatment step was unnecessary, it is not acknowledged to offer the invention a marked effect. Moreover, referring to the description, the reaction per se with the protease in the invention set forth in claims 1, 2, 4 and 5 encompasses the step of suspending the allergen in a phosphoric acid buffer solution, therefore extraction is carried out to some extent by the phosphoric acid buffer solution in this process, meaning that effectively an extraction step is carried out, and in this case, separating the extraction step as a pretreatment step is a matter which a person skilled in the art could select as necessary. In addition, document 2 sets forth a method of detecting allergen in a dust sample, and indicates that a protease substrate is exposed to a dust sample, therefore in the light of this disclosure it would be easy for a person skilled in the art to conceive of exposing room dust to a protease substrate.

Therefore the inventions set forth in claims 1, 2, 4 and 5 do not involve an inventive step in the light of documents 1 or documents 1 and 2.

#### Claim 3

It would be easy for a person skilled in the art to conceive of applying the same method to other allergens which are known to have protease activity, therefore the invention set forth in claim 3 does not involve an inventive step in the light of document 1 or documents 1 and 2.

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## Claims 7 and 8

It is a known technique to support a substrate on a porous substance in a reaction apparatus, therefore the invention set forth in claims 7 and 8 does not involve an inventive step in the light of document 1 or documents 1 and 2.

## Claims 9 to 17

The invention relating to an apparatus merely describes, in terms of an apparatus, the method of measuring the quantity of allergen set forth in document 1. In addition, by specifying that a pre-treatment step is not carried out in a method by referring back to claim 1, this does not specify an apparatus in such a manner as to be able to discriminate from the configuration of the apparatus used in a method which carries out pre-treatment.

Therefore the invention set forth in claims 9 to 17 does not involve an inventive step in the light of document 1.

## Claims 18 to 20

Document 1 indicates that a coloring substrate containing N-benzoyl-DL-alginin-p-nitroanilide, which is a pigment having amino acid amido-bonded to an amino group, and it is common practice in analysis to carry out detection according to change in color, therefore it would be easy for a person skilled in the art to conceive of using the different known pigments.

Therefore the invention set forth in claims 18 to 20 does not involve an inventive step in the light of document 1 or documents 1 and 2.

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Claims 21 to 26

Document 1 indicates that a coloring substrate containing N-benzoyl-DL-alginin-p-nitroanilide which is a pigment having amino acid amido-bonded to an amino group, and it is common practice in analysis to carry out detection according to change in color, therefore it would be easy for a person skilled in the art to conceive of using the different known pigments.

Therefore the invention set forth in claims 21 to 26 does not involve an inventive step in the light of document 1 or documents 1 and 2.